UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,104	03/24/2004	Benjamin Atkinson	12180/4	4159

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EXAMINER
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ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/808,104	ATKINSON, BENJAMIN
	Examiner	Art Unit	
	KRISTINE K. RAPILLO	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>24 March 2004</u>.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>1-24</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>1-24</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on <u>24 March 2004</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date <u>9/16/2004; 2/21/2006</u>.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claims 1 -24 are pending.

Claim Rejections - 35 USC § 101

1.   35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2.   Claims 1 – 7 and 9 – 10 are rejected under 35 U.S.C. 101 because the claimed invention is

directed to non-statutory subject matter. The applicant used the term "modules" to reference both

software (paragraphs [0032], [0037], and [0039]) and hardware (paragraphs [0032] and [0039]). The

applicant does not meet the criteria for a special definition of "module" in the specification. A module is

well known in the art as software, thus, the Examiner has treated "module" as software. As such, the

modules described in claims 1 - 7 and 9 - 10 are rejected under 35 USC 101 because it is not directed to

an apparatus, rendering it non-statutory.

Claim Rejections - 35 USC § 102

3.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for

the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4.   Claims 8 and 11 - 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Vonk et al.

(U.S. Publication Number 2006/0235280 A1), herein after Vonk.

        In regard to claim 8, Vonk teaches an evidence-based extender system, comprising:

- a means for communication a plurality of protocols for providing professional services (paragraphs [0008] and [0071]). Vonk teaches a computer program and system which provides evidence based protocols for the treatment guidance by a physician extender (i.e. nurse practitioner);
- a means for selecting a protocol from among the plurality of protocols, thus defining a selected protocol, wherein the means for selecting is in communication with the means for communicating (paragraphs [0142] through [0149], Figures 5A and 5B). Vonk discloses an electronic system which allows a user (paragraph [0138]) to select a protocol based on recommendations of the computer program and system; and
- a means for receiving the selected protocol in communication with the means for selecting (paragraph [0146]).

In regard to claim 11, Vonk teaches a computer readable medium comprising computer-executable instructions for implementing an evidence-based extender system for providing a professional service to a recipient through an extender (paragraph [0156]), the evidence-base extender system comprising:

- a protocol selection module receiving a plurality of protocols and data relating to the recipient's need for the professional service, and selecting the protocol from among the plurality of protocols according to the data relating to the recipient's need for the professional service (paragraphs [0142] and [0149]); and
- an extender feedback loop in communication with the protocol selection module and the extender and communicating the data relating to the recipient's need for the professional service to the protocol selection module (paragraphs [0141] through [0149]).

In regard to claim 12, Vonk teaches an evidence-based method for providing a professional service to a recipient through an extender, comprising:

- providing a plurality of protocols relating to the professional service (paragraphs [0008] and [0071]);

- collecting data from the recipient relating to a need for the professional service, thus creating need data (paragraphs [0037] and [0038]);

- selecting a protocol from among the plurality of protocols according to the need data, thus defining a selected protocol (paragraphs [0142] through [0149]); and

- providing the professional service to the recipient through the extender according to the selected protocol (paragraphs [0071], [0079], and Figures 5A and 5B).

In regard to claim 13, Vonk teaches the method of Claim 12, wherein the need data is collected by the extender (paragraphs [0037] and [0038]).

In regard to claim 14, Vonk teaches the method of Claim 12, wherein the selected protocol is selected by an evidence-based system (paragraphs [0071] and [0090]).

In regard to claim 15, Vonk teaches the method of Claim 14, further comprising providing a professional module, through which the plurality of protocols are provided to the evidence-based system (paragraphs [0071] and [0090]).

In regard to claim 16, Vonk teaches the method of Claim 14, further comprising providing an extender module, through which the need data are provided to the evidence-based system (paragraph [0142] and Figures 2 and 4). Figures 2 and 4 illustrate the step of obtaining patient data. The information obtained from the patient is entered into the evidenced based system.

In regard to claim 17, Vonk teaches the method of Claim 12, further comprising collecting data relating to a provision of the professional service according to the selected protocol, thus creating protocol application data (paragraph [0069]). The protocol application data is applying the protocols

recommended when providing a medical service, therefore, Vonk teaches this limitation by disclosing an invention in which the accumulation of data (from patient monitoring and assessment) is used to modify or adjust protocols.

In regard to claim 18, Vonk teaches the method of Claim 17, further comprising determining an efficacy of the plurality of protocols as a function of the protocol application data (paragraph [0076]).

In regard to claim 19, Vonk teaches the method of Claim 17, wherein the protocol application data is collected by the extender (paragraph [0069]).

In regard to claim 20, Vonk teaches the method of Claim 17, further comprising adjusting the selected protocol to create an adjusted protocol in response to the protocol application data (paragraphs [0040], [0041], and [0043]).

In regard to claim 21, Vonk teaches the method of Claim 20, wherein the selected protocol is adjusted by an extender-based system (paragraphs [0041] and [0043]).

In regard to claim 22, Vonk teaches the method of Claim 20, wherein providing the professional services through the extender includes providing the professional services according to the adjusted protocol (paragraph [0041] and [0043]).

In regard to claim 23, Vonk teaches a method for providing a medical service to a patient through a physician extender, comprising:
- providing a plurality of treatment protocols relating to the medical service (paragraphs [0008] and [0071]);
- collecting data from the patient relating to a need for the medical service, thus creating need data (paragraphs [0037] and [0038]);

- selecting a treatment protocol from among the plurality of treatment protocols according to the need data (paragraphs [0142] through [0149], and Figures 5A and 5B); and

- providing the medical service to the patient through the physician extender according to the treatment protocol (paragraphs [0071], [0079], and Figures 5A and 5B).

In regard to claim 24, Vonk teaches a computer readable medium comprising computer-executable instructions for performing an evidence-based method for providing a professional service to a recipient through an extender (paragraph [0156]), the evidence-based method comprising:

- receiving a plurality of protocols and data relating to the recipient's need for the professional service (paragraphs [0008] and [0071];

- selecting a protocol from among the plurality of protocols according to the data, thus defining a selected protocol (paragraphs [0142] through [0149]), and Figures 5A and 5B); and

- communicating the selected protocol to an extender for providing the professional service to the recipient according to the selected protocol (paragraphs [0071], [0079], and [0141] through [0149]).

Conclusion

5.   The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Levy (U.S. Patent Number 7,076,437) discloses a process for consumer directed diagnostic and health care information for facilitating patient/health care provider interaction and communication regarding a diagnosis and treatment. The diagnosis and treatment are based on evidence based medicine.

- Rosenfeld et al. (U.S. Patent Number 6,804,656) discloses a system and method for providing continuous, expert network critical care services from remote locations. Health care providers can monitor and assess a patients well being based on standardized guidelines from remote locations.

- Schramm-Apple et al. (U.S. Publication Number 2004/0078211 A1) teaches a computer assisted
  and/or implemented process and system for managing and/or providing a medical information
  portal for healthcare providers. The invention provides diagnostic tools, educational tools, and
  reference tools which are accessible over the internet.

Any inquiry concerning this communication or earlier communications from the examiner should
be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can
normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke
Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this
application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application
Information Retrieval (PAIR) system. Status information for published applications may be obtained from
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or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-
1000.

KKR

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626